

**BIOARCTIC AB (PUBL)**  
**NASDAQ STOCKHOLM: BIOA B**

# Q2 Report

## April-June 2023

Stockholm, July 12, 2023

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*Gunilla Osswald, PhD, CEO*

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# LEQEMBI® (lecanemab) approved in the US – the world’s first fully approved disease-modifying treatment for AD

- On June 9, the FDA Advisory Committee voted unanimously confirming the clinical benefit of LEQEMBI
- On July 6, the FDA granted Eisai traditional approval for LEQEMBI for the treatment of Alzheimer’s disease
- The CMS announced that Medicare will provide broad coverage of LEQEMBI
  - according to the FDA approved label
  - provided that real-world evidence is collected in an existing easy-to-use patient registry





# Lecanemab has the potential to become the first anti-A $\beta$ antibody to receive full approval globally

## USA ✓

FDA granted Leqembi traditional approval July 6, 2023

CMS provided broader Medicare coverage following FDA traditional approval July 6, 2023

VHA provided coverage for Leqembi March 13, 2023

Eisai plans to submit s.c. formulation and maintenance dosing applications by Q1 2024

## Japan

Marketing authorization application submitted on January 16, 2023.

Granted priority review on January 30, 2023

Expected PMDA decision September 2023

## EU

Marketing authorization application submitted on January 9, 2023

Accepted for a standard review on January 26, 2023

Expected EMA decision Q1 2024

## China

Initiated Biologics License Application in December 2022.

Granted priority review on February 28, 2023

Expected NMPA decision Q1 2024

## Rest of World

Canada: Submission accepted May 14, 2023

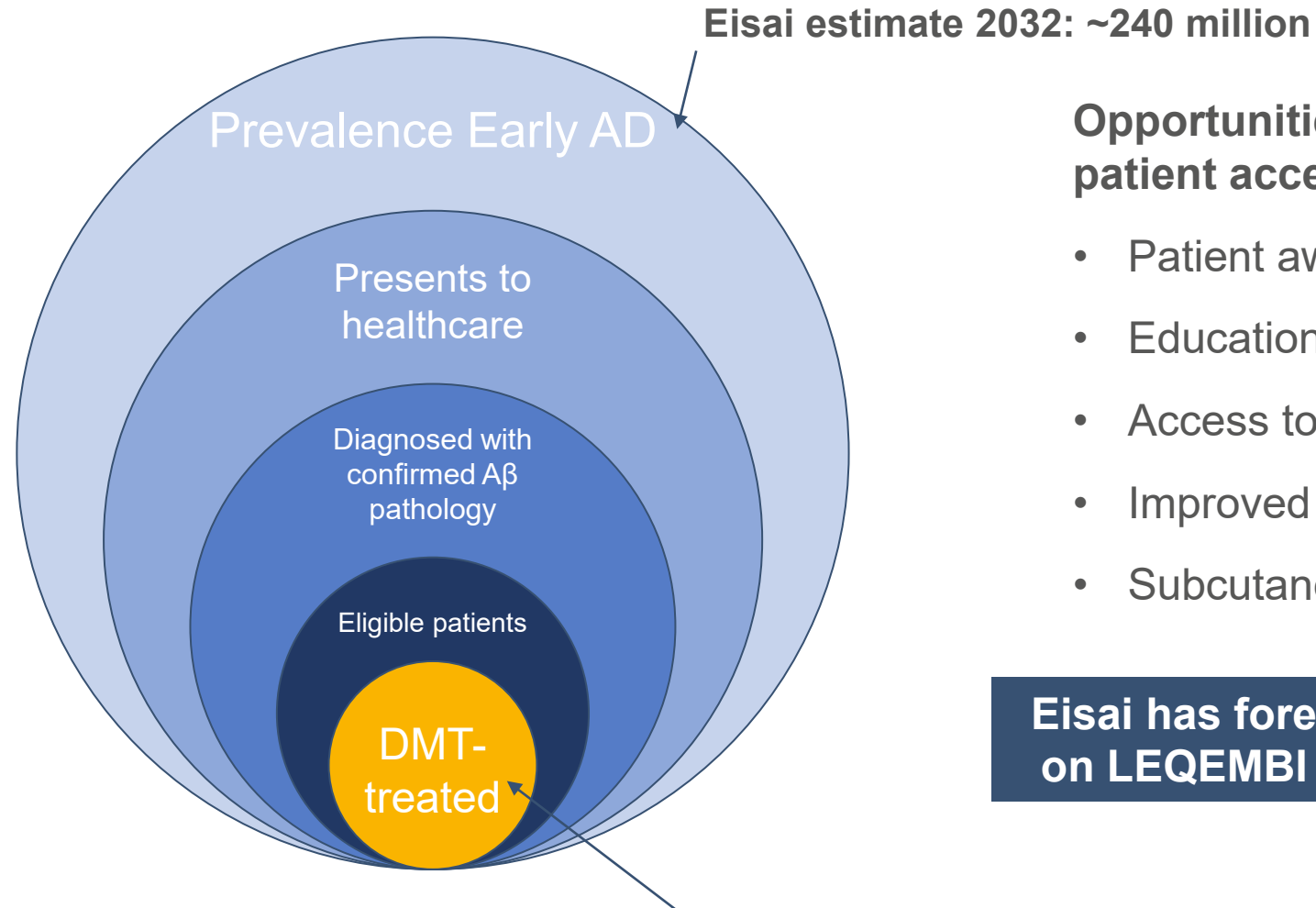
Great Britain: Application submitted May 19, 2023. ILAP designation

South Korea: Application submitted June 7, 2023

FDA – Food & Drug Administration  
CMS – Prescription Drug User Fee Act  
VHA – Veterans' Health Administration  
PMDA – Pharmaceuticals and Medical Devices Agency  
EMA – European Medicines Agency  
NMPA – National Medical Products Administration  
s.c. – subcutaneous



# Global estimates for future early AD patients treated with disease modifying treatments (DMTs) offer substantial room for growth










## Opportunities that could increase patient access:

- Patient awareness and less stigma
- Education at primary care
- Access to specialist care
- Improved diagnostics
- Subcutaneous formulation

**Eisai has forecasted 10,000 patients on LEQEMBI by the end of Q1 2024**

**Note:** Size of circles are not indicative of actual proportions  
Estimates based on internal calculations (Eisai/IQVIA)

# Partnership model to de-risk clinical development and optimize commercialization opportunity

Alzheimer's disease 			
<b>Partner track record</b>	<table border="1"><tr><td><p>Discovered and developed world's best-selling medicine for symptoms in Alzheimer's disease</p><p>Industry-leading pipeline in dementia area</p></td><td><p>Used to treat confusion (dementia) related to Alzheimer's disease</p></td></tr></table>	 <p>Discovered and developed world's best-selling medicine for symptoms in Alzheimer's disease</p> <p>Industry-leading pipeline in dementia area</p>	 <p>Used to treat confusion (dementia) related to Alzheimer's disease</p>
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<b>Collaboration and license</b>	<p>Milestones of up to</p> <h1>MEUR 101</h1> <p>remains to be received</p> <p>Royalties High single digit %</p> <p><b>BioArctic retains rights to lecanemab in other indications and option to market in the Nordics</b></p>		

The next potential milestones relate to approvals in Japan and the EU

# Attractive and well-balanced project portfolio

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) ( <i>Clarity AD</i> )	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>2</sup>					
	Lecanemab (BAN2401) ( <i>AHEAD 3-45</i> )	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>3</sup>					
	BAN2401 back-up	Eisai						
	BAN1503 (Trunc Abeta)							
	AD-BT2802							
	AD-BT2803 (Trunc Abeta with BT)							
	AD2603							
PARKINSON'S DISEASE	BAN0805 (alpha-synuclein)							
	PD1601 (alpha-synuclein)							
	PD1602 (alpha-synuclein)							
	PD-BT2238 (alpha-synuclein with BT)							
OTHER CNS DISORDERS	Lecanemab (BAN2401)							Down's syndrome <sup>4</sup> , Traumatic brain injury <sup>4</sup>
	ND3014 (TDP-43)							ALS
	ND-BT3814 (TDP-43 with BT)							ALS
	GD-BT6822 (GCase with BT)							Gaucher disease
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform							

1) Partner with Eisai for lecanemab for treatment of Alzheimer's disease since 2007. Eisai entered partnership with Biogen regarding BAN2401 (lecanemab) in 2014

2) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

3) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

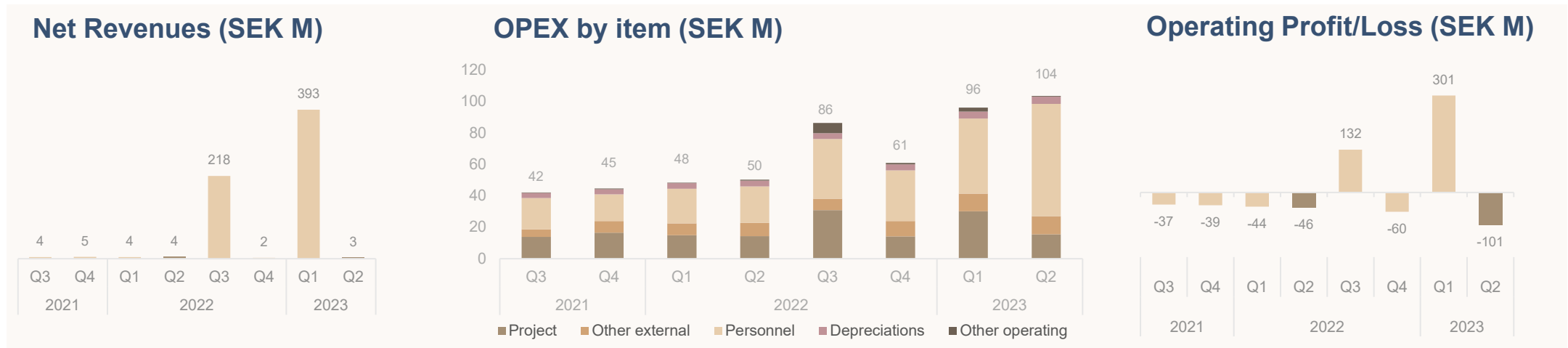
4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury



## Financial Summary



# Operating expenses 2023 within guidance



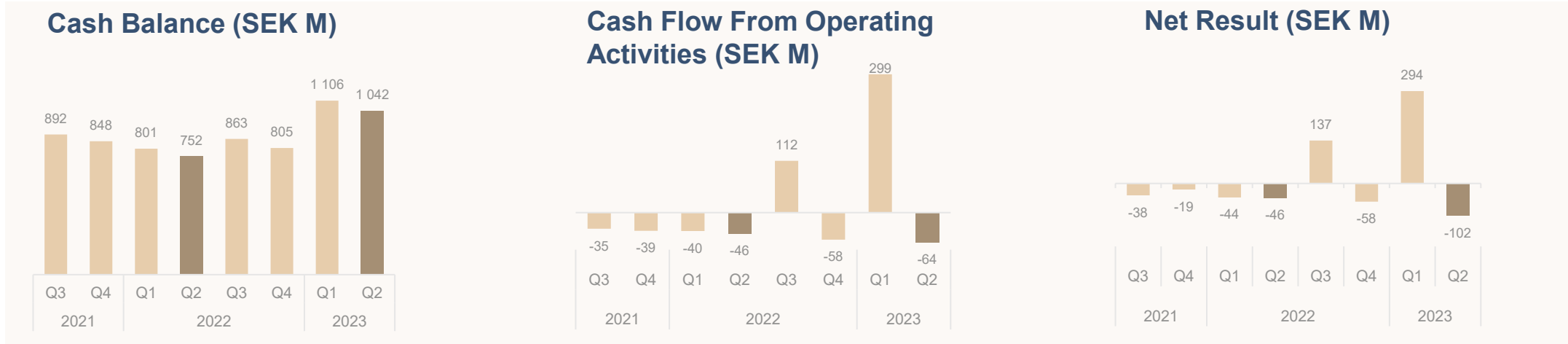
- Net revenues were SEK 3 M (4) for Q2 and SEK 397 M for the first half of the year
  - Three Q1 milestone payments of SEK 391 M (€ 35 M) in total
- Revenues will become less lumpy when royalties increase

- Operating expenses increased to SEK 104 M (50) in Q2 and SEK 200 M (98) Jan-Jun
  - Personnel costs increased to SEK 72 M (23) in Q2 mainly due to non-recurring effects,
  - Repurchase of stock options & other stock options costs with related social security provisions
- Costs will increase longer term
  - Build-up of commercial organization
  - Progression of project portfolio

- Operating loss was SEK 101 M (46) for Q2, profit of SEK 200 M (loss: 90) for the first half of the year

Full-year operating expense guidance reiterated:  
SEK 330 – 380 M for 2023, compared to SEK 246 M in 2022

# Strong financial position



- Cash balance amounted to SEK 1,042 M at the end of the second quarter
- Operating cash flow was a negative SEK 64 M (neg. 46) in Q2, positive SEK 235 M (neg. 85) for the first half of the year
- Net loss for Q2 was SEK 102 M (46), net profit of SEK 192 M (loss: 90) for the first half of the year

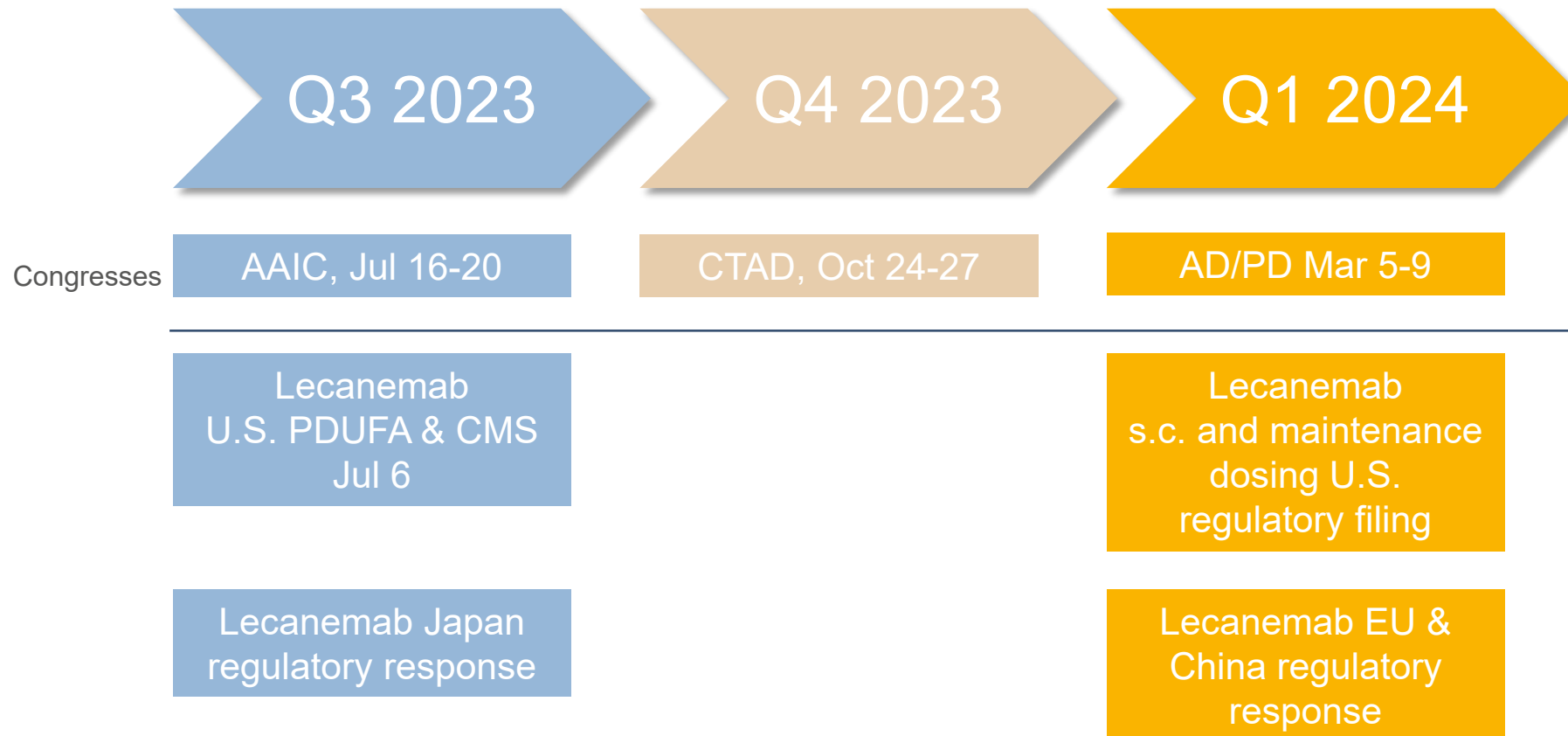
Milestones from Eisai of € 35 M in Q1 2023 further strengthened the financial position



**Upcoming news flow  
and closing remarks**

# Upcoming news flow

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PDUFA – Prescription Drug User Fee Act  
CMS – Centers for Medicare & Medicaid Services  
s.c. – subcutaneous





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BioArctic will, through world-leading innovative research, create drugs that improve the lives of patients with neurodegenerative diseases.

# IR team

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